Chapter 1

SUMMARY AND OPTIONS

Contents

Figure

Tables

Chapter 1

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Introduction

Few changes in the organization and provision of health care in the United States have been as dramatic as the shift away from hospital inpatient care that occurred during the 1980s. The past decade witnessed tremendous growth in such diverse activities as the establishment of ambulatory surgery centers, physicians' office laboratory testing, and freestanding cancer and cardiac centers (272a). An especially striking change was the development and maturation of a system to provide intensive and highly sophisticated medical treatments to patients in their own homes. Home drug infusion is one such medical therapy.

Almost unknown before the late 1970s, home drug infusion therapy (HDIT) is now a major industry with net revenues in the billions of dollars (289,307). Its growth is no accident. Many health insurers view this technology as a potential cost-saver. Providers view it as a welcome way of enhancing revenues. Market analysts view it as an investment opportunity. And patients view HDIT as an opportunity to resume a reasonably normal life while continuing sophisticated medical treatment.

But the widespread enthusiasm for this novel mode of medical therapy has been tempered in some cases by uncertainty about its potential applications and possible hidden costs. Medicare, the Nation's single largest health care insurer, has no benefit that explicitly covers HDIT. The Medicare Catastrophic Coverage Act of 1988 (MCCA, Public Law 100-360), which would have extended coverage to this benefit, was repealed before it was ever implemented. In 1990, in the context of continued interest in such a benefit, the Senate Committee on Finance asked the Office of Technology Assessment (OTA) to revisit the implications of covering HDIT under Medicare and to analyze alternative ways of paying for this therapy. This report was prepared in response to that request.[1]

Although the literature on HDIT is considerable, most of it deals either with specific techniques and procedures or with the feasibility of providing this service. To gather information for this study, therefore, OTA relied not only on the published literature but also on site visits to HDIT providers, discussions with persons involved in HDIT, and data supplied by individual insurers and providers (see app. A). The remainder of this chapter presents a summary of OTA's findings and conclusions and contains options for congressional consideration.

Summary and Conclusions

What Is Home Drug Infusion Therapy?

OTA found that HDIT is a medical therapy that involves the prolonged (and usually repeated) injection of pharmaceutical products, most often delivered intravenously (into a vein) but also sometimes delivered via other routes (e.g., subcutaneously or epidurally).[2] Some drugs, such as antibiotics, maybe infused over relatively short periods (e.g., 30 minutes) a few times each day; others, such as analgesics to relieve extreme pain, maybe administered around the clock. All of these infusion therapies have in common the need for specialized equipment and supplies and skilled nursing care in order to be administered safely. At present, patients or their family caregivers[3] are usually, although not always, trained to perform some of these needed skilled services themselves.

Until the end of the 1970s, drug infusion therapy was almost always a hospital inpatient procedure. The components of care associated with this therapy (e.g., inserting the needle in the vein, regulating the infusion, monitoring the patient, and changing the dressing (bandage) around the needle's entry site) usually required the meticulous care of trained nurses to avoid life-threatening infections and allergic reactions. Indeed, these requirements still exist. During the late 1970s, however, a few hospitals and

[1] Another report prepared in response to the same general request, *Outpatient Immunosuppressive Drugs Under Medicare, was* released in September 1991.

[2] "Subcutaneously" refers to injections under the skin; "epidurally" refers to injections into the epidural space around the spinal cord.

[3] In this report, "family caregivers" refer to both immediate family members and other unpaid individurds (e.g., close fiends) who are trained to perform some of the nursing-related infusion services.

physicians began to train highly selected patients with prolonged infections (or their caregivers) to perform some of these procedures themselves at home (16,188,290,324). In the early 1980s, with the publication of successful results from some of these programs and the implementation of payer-induced constraints on hospital inpatient care, a new mode of therapy-and a new industry-was born.

This report deals with the drug and biological infusion treatments (including blood transfusions) being used in the home but not yet explicitly covered by Medicare in that setting. Medicare does cover total parenteral nutrition (TPN) in the home for individuals with long-term disabilities that prevent them from being able to digest food.[4] TPN has many similarities to the therapies discussed in detail in this report, and many providers of HDIT also provide TPN and other nutritional products and services. In fact, nutritional therapies still produce a substantial proportion of the revenues for the home infusion industry (34,307). However, because the purpose of this report is to examine other noncovered infusion therapies, TPN is discussed only as it is relevant to the issues surrounding HDIT.

Uses and Recipients of Therapy

The number of patients who currently receive drug infusion therapy at home is unknown but probably in the vicinity of a quarter of a million persons per year. A 1987 market analysis estimated that in the previous year, approximately 39,000 such patients received home treatment, and it predicted that over 225,000 would do so in 1990 (289). A more recent investment report estimated the 1990 market at roughly 200,000 patients (275). Given that the market has continued to grow, a 1991 estimate of between 200,000 and 250,000 persons in HDIT during the year seems reasonable.[5]

Most HDIT patients presently served are non-elderly adults. Two HDIT providers with data on patient age report that the great majority of their patients are between the ages of 18 and 65 (3,250). About 15 percent of each provider's patients are elderly (age 65 or over), a figure that includes some patients on nutritional and other infusion therapies as well as HDIT A survey of six national infusion specialty firms found that slightly less than 18 percent of patients are age 65 or over (256); again, this number included patients receiving TPN. Conversations with other providers suggest that many of them consider elderly patients on HDIT to be relatively rare. Thus, excluding patients on TPN, a "best guess" estimate is that about 10 to 15 percent of current HDIT patients are elderly. Based on these very rough assumptions, OTA estimates that between 20,000 and 35,000 elderly individuals received HDIT in 1991.

HDIT patients fall into a few major groups and many smaller ones. The first and largest group is composed of those patients who require intravenous (IV) drug therapy for infections (e.g., bone infections) that require prolonged treatment and are not usually susceptible to oral drugs. Persons with cancer make up another major group; these individuals may need not only antineoplastic drugs to combat the cancer but also antibiotics, analgesics, hydration, and other infusion therapies at times. A third category of HDIT recipients are those with AIDS. Like persons with cancer, those with AIDS may be treated with any of a number of therapies (e.g., antibiotics, antifungal medications, and blood transfusions) depending on their particular medical conditions.

Other categories of individuals whose conditions are sometimes treated with home infusion therapies include individuals with congestive heart failure, persons with certain immune disorders, pregnant women receiving infusions of drugs to prevent premature labor, and patients with severe anemia or other blood disorders who need blood transfusions. Some of these treatments are experimental or are not yet widely available in the home.

Components of Therapy

Drugs-At present, antibiotics and other anti-infectives are the most common drugs involved in home infusion therapy. Based on estimates by market analysts and other sources, it appears that about two-thirds of current drug orders for HDIT involve anti-infective drugs (34,193,193a).[6] Ap-

[4] "Parenteral" refers generally to methods of administration that bypass the digestive tract. TPN is nutrient solution that is administered intravenously.

[5] This number probably includes some individuals receiving outpatient clinic-based rather than home therapy, since the market analyses did not distinguish clearly between these two settings.

[6] Although antibiotics are responsible for about two-thirds of HDIT drug orders, only about half of HDIT patients receive antibiotics (193%256).

proximately another 15 percent of HDIT drugs are antineoplastics or pain medications. The diverse remaining group of drugs makes up somewhere between 10 and 20 percent of HDIT at present.

Equipment—Whatever the route of administration, HDIT requires two crucial pieces of equipment: the access device that is inserted into the body (e.g., an N catheter), and the Infusion device that controls the rate of drug flow. The choice of this equipment depends on the patient's condition, the length and type of drug therapy prescribed, and the preferences of the patient and provider. The methods of access and infusion control chosen, in turn, can affect the need for supplies and for nursing care and the overall cost of the therapy.

The continual emergence of new home infusion therapy technologies broadens the types of patients who can be treated at home and changes the parameters of service delivery. Some recently developed technologies have reduced the amount of skilled nursing intervention required for patients at home and made it easier for patients to self-administer complex drug regimens (see ch. 3). Nonetheless, despite the development of increasingly sophisticated infusion pumps over the past decade, less expensive gravity drip systems are still safe and appropriate for some patients receiving antibiotic and hydration therapies.

Services-HDIT involves a complex array of services that must be coordinated with each other. They also must be coordinated as a unit with any other home health care services and supplies the patient receives. Although the responsibilities and involvement of particular types of personnel vary greatly among HDIT providers, all HDIT requires that at least certain core services be provided in some way.

. *Pharmacy services* involve, at a minimum, compounding the drugs to be infused and being available to respond to emergencies and questions regarding the therapy.[7] Pharmacists' responsibilities often also extend to participating in patient education, **anticipating drug side** effects, dealing with nonemergency issues relating to the therapy, monitoring patients via conversations with nurses or patients themselves, monitoring laboratory results, and collaborating with physicians on prescription changes.

Photo credit: Ivion Corp.

New technologies such as this multiple-drug infusion pump allow patients to self-administer complex drug regimens at home.

- *Nursing services* include educating the patient and family caregiver regarding administration of the infusion and care of the infusion site,[8] dressing and infusion site changes, and in-home monitoring of the patient's health status. Nurses may perform a wide variety of other functions as well, ranging from overseeing the actual infusion to patient assessment and care coordination.
- *Physician services* provided by the patient's physician include ordering the home care, prescribing the therapy, overseeing the patient's progress through patient visits and monitoring laboratory and clinical reports, dealing with emergencies, and making changes in the therapy as needed. In practice, the extent of physician involvement in HDIT appears to be highly varied. Some physicians take a very active role—for example, seeing all patients in person at least twice a week and holding extensive telephone conversations with nurses and pharmacists involved in the therapy—

[7] **Larger infusion providers often employ pharmacy technicians to assist pharmacists in compounding drugs.**

[8] **Pharmacists, social workers, or other professionals may also be involved in aspects of patient assessment and education.**

while others have much less contact with the patient and professional caregivers during the course of the therapy.

- *Laboratory services are* necessary to monitor the patient's status and response to therapy as detected through blood samples and other tests. Most HDIT providers do not have in-house laboratories.

Based on numerous site visits and conversations with HDIT providers, patients, and others, it appears that most HDIT providers are skilled at coordinating the services specific to the home infusion therapy. For patients receiving other home care as well, however (e.g., basic home nursing, physical therapy, or respiratory therapy), the complex of HDIT-specific services must also be coordinated with these home health care services. Such coordination across different home care services may be particularly important for Medicare patients, but it is a service many HDIT providers are not currently well-equipped to offer.

Many of the tasks necessary for HDIT would be performed by a skilled nurse in a hospital setting. At home, however, these tasks can often be performed by the patient or a family caregiver who has been taught the proper techniques by a qualified health professional. Medicare beneficiaries are more likely than other patients to have disabilities that limit their ability to learn or perform infusion techniques and other most basic self-care tasks (e.g., dressing and bathing). Their spouses may also have functional limitations. Thus, OTA concludes, Medicare patients are more likely than other patients to require paid assistive services in order to receive medical care such as drug infusion therapy at home. If the frequency and intensity of professional services required by a home infusion patient are great (e.g., a functionally disabled patient on a 4-dose/day antibiotic regimen who has no family caregiver available), a skilled nursing facility (SNF) or other nonhospital institutional setting that offers 24-hour care might be a more reasonable alternative to hospitalization than traditional home care.

Current Medicare Coverage of HDIT

Medicare pays for "medically necessary" services and supplies associated with drug infusion when it takes place in hospitals, outpatient clinics, or physicians' offices. (Some of these settings (e.g., physicians' offices) may be subject to locally set limitations on infusion payments and coverage.)[9] Medicare does *not* have an HDIT benefit; the need for this therapy when provided at home does not qualify a beneficiary for Medicare coverage of any particular items. However, certain components of HDIT are sometimes covered by Medicare under existing benefits for beneficiaries in their own homes.

The core nursing services used in HDIT are sometimes covered by Medicare under the Part A home health benefit, while pharmacy services and supplies are sometimes covered under the Part B durable medical equipment (DME) benefit (table 1-1).[10] The home health benefit covers intermittent skilled nursing care, and home infusion therapy patients' need for such care would also qualify them for additional home health aide and therapy services. The Part B DME benefit covers reusable equipment such as infusion pumps and the supplies associated with such equipment. Some carriers also cover a wide variety of drugs when used in an infusion pump (365) (see ch. 6).

Current coverage of the core HDIT services has a number of problems. First, it is incomplete and fragmented; coverage is piecemeal, administratively split between Part A and Part B fiscal intermediaries (FIs-Medicare's administrative contractors), and highly variable. Some carriers, for example (the Part B FIs), interpret the DME benefit to include even coverage for antibiotics administered by gravity drip (365). Other carriers almost never pay for any drug through this benefit. Second, there are no guidelines for who can provide HDIT, and thus there are no minimum quality standards for such providers under Medicare.

A third problem with the existing benefit structure is that it tends to discourage the most independently functional patients from leaving the hospital. To be

9 Infusion is also sometimes provided in hospices and skilled nursing facilities (SNFs). Although Medicare "covers" the infusion in these instances, payment rates to hospices and SNFs are generally unaffected by whether the service is performed. These providers thus have a strong disincentive to offer infusion while a patient is served by the hospice or SNF.

10 Only the Part B DME benefit sometimes encompasses drugs. The Part A DME benefit that is subsumed under the home health care benefit specifically excludes drugs from coverage.

Table l-l—Existing Medicare Benefits Applicable to Home Drug Infusion Therapy

Benefit	Components of HDIT covered	Selected relevant limitations
Part A		
Home health services	Nursing, supplies,durable medical equipment (DME).	Patient must be homebound. Drugs *not* covered under home health DME benefit.
Hospice	Those components the hospice chooses to provide to its in-home patients.	Providing infusion does not affect hospice's flat-fee payment rate.
Part B		
Durable medical equipment	Pumps, other DME, supplies, selected drugs.	Drug coverage varies greatly by carrier. Disposable "pumps" not considered DME.
Laboratory services	Laboratory tests.	
Physician services	Physician visits, some office-based infusion therapy services provided to home patients.[a]	No payment for administrative responsibilities; may be local limits on office-based therapy.
Hospital outpatient services	On-site outpatient infusion therapy services provided to home patients.[a]	—

[a]Some patients, for example, may undertake their own daily routine infusion-related care but return to an outpatient clinic or office for more specialized services such as catheter site changes.

SOURCE: Office of Technology Assessment, 1992.

eligible for home health nursing benefits, for example, beneficiaries must be homebound-i.e., unable to leave their homes without some kind of assistance. And while nearly all carriers at least sometimes pay for infused cancer therapies (analgesics and antineoplastics) as part of the DME benefit, considerably fewer pay for antibiotics-and some of the latter pay only when a patient is so ill as to be already receiving other infusion therapies.

In addition to the core pharmacy and nursing components, Medicare routinely pays for the laboratory services associated with HDIT as part of the standard Part B laboratory benefit (table l-l). Medicare also routinely pays for physician services, including physician visits (home or office) to monitor the status of HDIT patients. However, the program does not pay for telephone or administrative time of physicians overseeing home care plans. Because of the level of medical monitoring needed for HDIT patients, the amount of time spent in these activities can be substantial. Consequently, the lack of payment for these services-and the relative generosity of payment for daily visits to hospitalized infusion patients—is a disincentive for physicians to discharge some patients to home care under the current system.

The Home Drug Infusion Industry

The development and shape of the HDIT industry has been influenced by two important factors. First, the development of the industry has followed past changes in Federal policies. Medicare coverage for home parenteral and enteral nutrition (begun in 1977) and the implementation of prospective payment for Medicare inpatient services (in 1983) both contributed to the explosion in the home infusion industry that occurred during the first half of the 1980s. If Medicare should choose to cover and pay for HDIT in the future, how it does so may have a similarly profound impact on the shape of the industry. Not only could the number of elderly patients being treated at home expand far beyond the estimated 20,000 to 35,000 now served, but Medicare's policies could serve as a model (or a caution) for other public and private insurance programs.

Second, the growth in the home infusion service industry-those organizations that provide the nursing and pharmacy services and products directly to patients—has been enabled by the technologies that have permitted drug infusion therapy to be self-administered in the home. Increasingly sophisticated infusion pumps, administration kits, therapy protocols, venous access devices, and drugs that need be

Photo credit: CADD-PCA@ Ambulatory Infusion Pump Model 5800, Pharmacia Deltec Inc., St. Paul, MN

Sophisticated infusion pumps have been developed for specific segments of the HDIT market. This pump delivers a constant dose of pain medication, with a special button that allows the patient to self-administer occasional larger doses as needed up to a preprogrammed maximum amount.

administered only once or twice a day have all contributed to the feasibility of home therapy for an ever-growing number of patients.

As manufacturers have developed new supplies and equipment, providers have become adept at incorporating them and marketing both products and services to patients, physicians, and payers. Provider success at encouraging HDIT, in turn, stimulates even greater effort in developing technologies for this market.

The present assortment of HDIT providers includes a few large (national or regional) infusion specialty providers that offer most of the basic services and products associated with drug infusion therapy, including pharmacy supplies and services, equipment and medical supplies, and specialty nursing. In addition, there are a multitude of smaller regional and local providers, for most of whom HDIT is a relatively small proportion of a larger business. These local providers include home health agencies (HHAs), community pharmacies, physicians, medical equipment suppliers, and hospitals.

In many cases, smaller providers may offer only one or two components of the therapy directly. A patient from a small town who is on HDIT, for example, might receive infusion-related nursing from the local HHA, pharmacy products and services from the local pharmacy, and an infusion pump from the local medical equipment dealer. In fact, it appears that many HDIT providers contract with at least one other type of provider to provide some components of the therapy. Where patients need routine as well as infusion specialty nursing, the routine nursing is ah-nest always performed by a separate agency (except where the HHA itself is also the primary home infusion provider) (see figure l-l).

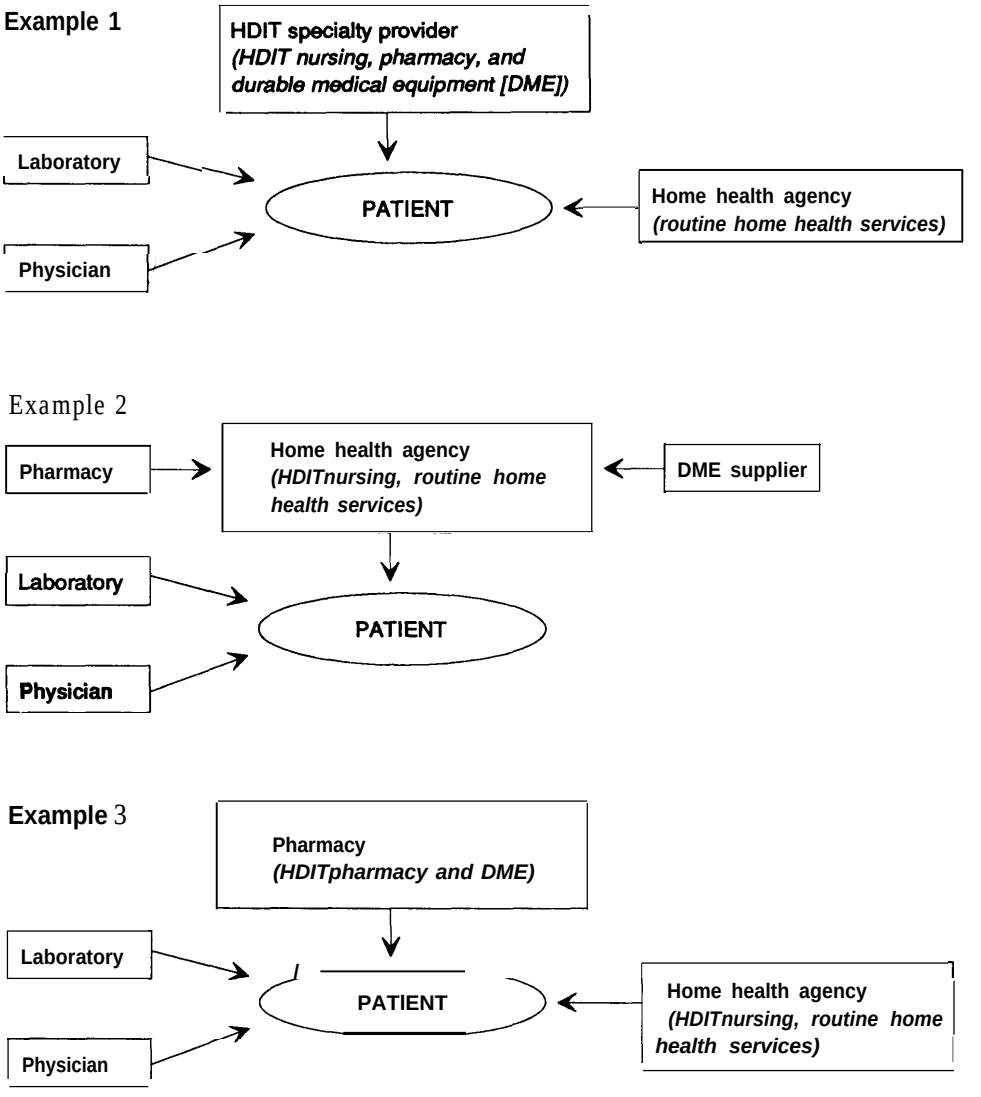
The continually expanding revenues and, apparently, relatively high profit margins that have been enjoyed by the HDIT industry thus far have facilitated and encouraged the entry of new providers into the marketplace, expanding access to HDIT services and stimulating the development of new products. The increasing revenues are in part due to the liberal reimbursement that these companies have often been able to garner. Future controls over what companies can charge Medicare patients for home infusion therapy might slow the growth of certain sectors of the marketplace.

Is HDIT Safe and Effective?

Home drug infusion technologies have become commonplace. Most are effective and can be performed safely in the home when patients are carefully selected and trained and home care providers have adequate procedures and qualified staff. However, HDIT is not without substantial risks. When those qualifications are not met, OTA believes that patients on home therapy can be at a high risk of adverse events, including severe infection, shock, and even death.

In a few cases, the effectiveness of the drug itself used in HDIT is open to question. For example, existing studies on long-term dobutamine, a drug sometimes used to treat severe congestive heart failure in the home, suggest that this use of the drug may actually be harmful for some patients (see ch. 2). Immune globulin is an example of a product that has some clearly indicated uses, but that is also finding use in a variety of conditions where its effectiveness is less well established (and its costs high).

Figure l-l—Three Examples of Potential Relationships Between Providers and Patients Receiving Both Home Drug Infusion Therapy (HDIT) and Routine Home Health Services



SOURCE: Office of Technology Assessment, 1992.

Infusion therapy carries some risks regardless of the setting in which it occurs. Although most complications (e.g., vein irritation at the catheter entry site) are minor if recognized and treated immediately, conditions such as sepsis (systemic infection) and shock (from drug allergic reactions) can be life-threatening. Mechanical complications of the infusion (e.g., air entering the vein) and equipment malfunctions can also cause serious medical problems.

Some risks (e.g., the risk of acquiring g serious secondary infections) are probably lower when patients are home than when they are in the hospital. On the other hand, in the hospital, constant nursing supervision and rapid access to sophisticated emergency care ameliorates many of the other risks of infusion therapy. In the home, there is rarely continuous professional monitoring, and emergency care is not available on site. Consequently, the most clearly appropriate drugs for the home are those in

which life-threatening side effects or complications are rare, and those in which most side effects are apparent when the first dose is given (which can be monitored in a hospital or physician's office). Many antibiotics fit this description. Although infused analgesics and antineoplastics require more care to be used safely at home, the need for these therapies lifelong by many patients may justify their use in this setting.

OTA found that, in addition to the choice of drug, patient selection and provider procedures are crucial to making the level of risk at home comparable to that in the hospital. Patients who are medically unstable (e.g., have a very high fever) are not appropriately discharged from the hospital. In addition, patients who have no supportive family caregivers, who are unable to understand and carry out infusion therapy procedures, or who are unwilling to continue therapy at home are at high risk of complications and are poor candidates for home care. Provider procedures, such as performing rigorous patient selection, requiring special pharmacist and nurse training, carrying anaphylaxis treatment kits, and requiring 24-hour on-call pharmacist and nurse availability, minimize risk. Physician involvement is also critical to the safe and effective delivery of HDIT services.

The relationship between patient suitability, provider procedures, and medical risk in HDIT warrants quality assurance efforts on the part of the Federal Government in the event of Medicare coverage. Quality assurance efforts should include some level of case review to monitor instances of possible poor-quality patient care. They should also include explicit and stringent conditions of participation that HDIT providers must meet to receive Medicare reimbursement. Such conditions can assure that although some direct patient care services may be performed under contract, certain functions (e.g., initial patient assessment, service coordination, periodic drug regimen review, clinical recordkeeping, and providing an ongoing and emergency point-of-contact for patient) remain the responsibility of the "primary" HDIT provider. This "primary" provider is the one that undertakes the responsibility for coordinating the HDIT and that subcontracts or arranges with others to provide those HDIT services it does not provide in-house.

Issues and Options for Medicare

Implications of Medicare Coverage

Substantial numbers of Medicare patients are currently receiving HDIT, although the exact number is unknown. As described above, OTA estimates that roughly 20,000 to 35,000 persons age 65 and over will receive this therapy in 1991, and of elderly persons the great majority is eligible for Medicare. In addition, some disabled Medicare beneficiaries probably receive HDIT

Many of the Medicare beneficiaries receiving HDIT at present have other insurance (e.g., private insurance or Medicaid) that presumably pays for the therapy. However, as described above, despite the lack of an explicit Medicare HDIT benefit, some beneficiaries do receive Medicare coverage for some of the components of HDIT some of the time. The frost decision regarding Medicare coverage of HDIT is whether to pass a comprehensive benefit.

Considerations regarding whether an HDIT benefit should be enacted are addressed in option below. Options 1 through 9 (summarized in table 1-2) then discuss some of the different forms such a benefit might take. Finally, options 10 through 19 present possible research and demonstration projects that might inform Federal policymakers regarding various aspects of HDIT These options, which could be implemented in either the presence or absence of a Medicare HDIT benefit, are summarized in table 1-3.

Option O: Enact a home drug infusion benefit under Medicare.

Many patients would prefer to receive drug infusion therapy at home rather than in the hospital, and when appropriate precautions are in place they receive good quality care. At present, however, existing "back door" mechanisms through which specific components of HDIT are currently covered result in fragmented and inconsistent coverage in which there are no qualifications required by Medicare for HDIT providers and no quality control of the overall set of services received by the patient. Thus, a Medicare HDIT benefit would offer enhanced patient benefits compared with the current policy.

The cost implications of extending Medicare coverage are less straightforward. In the short run, the addition of this benefit would almost certainly

Table l-2—issues and Options for Covering Home Drug Infusion Therapy (HDIT) Under Medicare

Basic Issue: Should Medicare cover HDIT?
Option O: Enact a home drug infusion benefit under Medicare.

(If so:)

issue 1: What routes of drug admlnlstratlon shouldbe covered?
Option 1A: Cover only intravenously administered drugs.

Option 1 B: Cover both intravenous and other routes of parenteral administration.

Issue 2: What drugs and conditions should be covered?
Option 2A: Cover drugs and conditions specified on a list devised by the Health Care Financing Administration (HCFA).

Option 2B: Permit fiscal intermediaries to determine specific covered drugs and conditions, based on general coverage categories and guidelines from HCFA.

Issue 3: Who should be eligible for the benefit?
Option 3A: Cover only patients who can self-administer their therapies (after initial instruction) or who have family caregivers to perform this service.

Option 3B: Extend coverage to all patients who can be safely treated at home, including patients who need assistance with their infusion-related or other home health care.

Option 3C: Extend coverage to patients who cannot self-administer, but limit the amount of assistive services such patients may receive.

Issue 4: Who should be able to provide and bill for HDIT?
Option 4A: For patients needing only HDIT, permit providers of different components of this therapy (e.g., pharmacy and nursing services) to bill separately for their respective components.

Option 4B: For patients needing only HDIT, require that a single certified home infusion therapy provider bill for all services received by that patient.

Option 4C: For patients needing both infusion and other home health services, permit a certified home infusion provider and the home health agency provider to bill separately for their respective services.

Option 4D: Require that the primary provider for patients needing both infusion therapy and other home services-i.e., the provider who coordinates services and submits a bill to Medicare-be a certified home health agency.

Issue 5: Where should a benefit be placed In Medicare's structure?
Option 5A: Make HDIT a Part A benefit.

Option 5B: Make HDIT a Part B benefit.

Option 5C: Make HDIT a benefit under both Parts A and B, depending on the patient's circumstance and concordant benefits.

Issue 6: Should benefit administration be consolidated?
Option 6: Require that the benefit be administered through a few regional fiscal intermediaries.

issue 7: What level of case review should be required, and by whom?
Option 7A: Do not require preauthorization for HDIT.

Option 7B: Require Peer Review Organizations (PROS) to preauthorize some or all HDIT patients.

Option 7C: Require fiscal intermediaries to preauthorize HDIT patients.

Option 7D: Require PROS to retrospectively review some home infusion patient claims.

issue 8: How should providers be paid for HDIT?
Option 8A: Pay for the various components of an HDIT benefit under existing payment mechanisms that apply to home health, durable medical equipment, and other benefits.

Option 8B: Pay for HDIT on the basis of actual costs, with a cap on the total costs allowed.

Option 8C: Pay a prospective per-diem rate for HDIT services.

issue 9: How should physicians be paid for HDIT-related services?
Option 9A. Pay physicians for their additional supervisory time in HDIT cases on the basis of existing fee-for-service methods.

Option 9B. Pay supervisory physicians a fixed rate (e.g., per patient or per day) for patients on HDIT.

Option 9C. Do not pay physicians for supervisory and advisory activities related to oversight of HDIT.

SOURCE: Office of Technology Assessment, 1992.

raise program costs, because Medicare cannot immediately recoup the financial benefits of shorter hospital stays. In the long run such a benefit could be cost-saving to the program, particularly if it were limited to independent patients who, when trained, needed little additional paid assistance. The benefit could be cost-raising in the long run, however, if Medicare were to pay for more costly home care in order to improve the quality of life during treatment for beneficiaries who need assistance to receive HDIT. The extent of long-run cost savings also depends on the ability of Medicare to bargain for low rates from providers, and its ability to identify patients who would be more costly at home and ensure that these patients are treated in alternative settings.

Covering HDIT would affect not only the Medicare program and HDIT providers and payers but also many facilities that are alternative sites of infusion therapy: skilled nursing facilities (SNFs), outpatient infusion providers, and hospitals. Outpatient clinics may be more appropriate settings than acute-care hospitals for some Medicare patients who need assistance with their infusion therapy, and SNFs may be more appropriate for many patients who need other assistive care as well. At present, however, SNFs have high occupancy rates and few empty beds, and most SNFs do not usually retain the

Table 1-3-Options for Conducting Research and Demonstrations Relating to Home Drug Infusion Therapy (HDIT)

Clinical studies
Option 11: Provide provisional or augmented coverage for drugs administered by HDIT providers participating in certain clinical studies.
Cost studies
Option 12. Examine the resource costs of providing HDIT and the economic characteristics of the HDIT industry.
Option 13. Examine the relative costs of providing drug infusion therapy in home and outpatient settings.
Option 14. Examine the use of basic home health services, and the need for infusion assistance, among elderly patients on HDIT
Payment studies
Option 15. Examine different potential methods of paying for HDIT.
Option 16. Examine the feasibility and effects of paying hospitals less than the full inpatient rate for patients subsequently discharged to HDIT.
Option 17. Examine alternative methods of paying for drug infusion therapy in skilled nursing facilities and hospital swing beds.
Option 18. Examine the effects of an HDIT benefit on rural and inner-city hospitals.
Quality studies
Option 19: Examine the outcomes of HDIT under various conditions (e.g., different types of patients and therapies) to determine which measures might be appropriately used as indicators of good- or poor-quality care.

SOURCE: Office of Technology Assessment, 1992.

in-house expertise to provide drug infusion therapy. They may be unwilling to accept drug infusion patients, or to treat existing patients in the nursing home, either due to lack of expertise or lack of reimbursement to cover the expense of intensive drug therapy.

For hospitals, covering HDIT would lead to lower payments in the future for some diagnosis-related groups (DRGs), to account for shorter average lengths of hospital stays and lower average costs in these DRGs. Hospitals unable to discharge patients home (e.g., due to the lack of a qualified home care provider in the area) would be disadvantaged despite their best efforts. This disadvantage will be minimized if these hospitals have "swing beds' '[11] to which they can discharge patients needing only drug infusion therapy and associated skilled nursing, and if they are adequately reimbursed for that care.

If current policies are unchanged, Medicare is likely to find itself paying for a substantial amount of HDIT in the future even in the absence of a defined benefit. Under current DME and home health rules, the actual coverage is increasing and will probably continue to do so, as Medicare's FIs use their discretion to cover drugs as well as the associated equipment, supplies, and nursing care. This coverage, however, will continue to be fragmented, uncoordinated, and inconsistent across areas. The absence of a coordinated benefit limits the ability of Medicare to assess, monitor, or influence the safety, quality, and effectiveness with which home infusion services are delivered.

Thus, OTA concludes that covering HDIT and placing defined requirements on providers and patients is likely to improve the quality of home care that Medicare patients receive. It may not save costs, however; to the contrary, it could easily increase Medicare spending. Program cost savings are probably more likely if the benefit places some restrictions on those who can use it.

Coverage Options

If Congress should decide to make HDIT a Medicare benefit, it must first decide what and who should be covered. Options 1 through 3 present possible alternative decisions regarding three coverage issues:

1. whether coverage should extend beyond IV administration to other forms of parenteral drug administration;
2. what drugs and medical conditions should be covered and how these coverage decisions should be made; and
3. whether patients who need assistance with their care (and have no family caregiver) should be eligible for the home infusion benefit.

Route of Administration

Option 1A: Cover only intravenously administered drugs.

Option IB: Cover both IV and other routes of parenteral administration.

[11] Swing beds are acute-care beds designated by a hospital to provide either acute or long-term care services. Medicine and Medicaid pay for care provided to swing-bed patients in qualifying rural hospitals.

Most drugs infused at home (e.g., most antibiotics) are administered intravenously. However, depending on the drug and the condition of the patient, drugs may also be infused into an artery (intraarterially), under the skin (subcutaneously), into the muscle (intramuscularly), into the abdomen (intraperitoneally), or into the areas around the spinal cord (epidurally or intrathecally).

In some cases, one of these latter modes of delivery is used because the drug itself is most effective, or causes the least complications, if administered in that manner. In a few cases, a drug may usually be most effective when administered intravenously, but a patient maybe unsuitable for IV therapy (e.g., because the veins are very fragile). Such a patient might instead get the drug by the next most favorable route (e.g., subcutaneously) .12

Choosing to cover drugs only if they are administered intravenously (as would have been the case under the MCCA) has the virtue of applying a rule that is unambiguous, simple to administer, and applicable to many of the drugs most amenable to home therapy (e.g., most antibiotics). Its drawback is that it will also exclude many drugs and patients that would otherwise be equally qualified for home therapy. It would also inhibit the use of drugs that might in the future be found equally effective and safer if given by some route other than IV.

In contrast, covering a broad general category of infused drugs in statute gives much greater latitude to the Health Care Financing Administration (HCFA) (or its FIs) to cover drugs delivered by means other than IV when such coverage is deemed appropriate at home. The great virtue of this option is its flexibility and adaptability to future changes in drug and device technology that make alternative delivery modes attractive. Its drawback is that it could be interpreted to include a wide variety of drugs and patients that were not intended to be included in a benefit. "Infusion," for example, might be applied to slowly administered liquid oral medications, or to drugs administered through a rapid injection as a one-time "shot. '

One strategy to address this drawback would be to define "infusion" carefully in statute, either by specifying excluded categories (e.g., fluids administered into the digestive tract) or included categories (e.g., intravenously and subcutaneously administered fluids injected over a period of at least 10 minutes). A second strategy would be to leave the definition of "infusion" and the delivery routes it encompasses up to HCFA.

Drugs and Conditions Covered

Option 2A: Cover drugs and conditions specified on a list devised by HCFA.

Option 2B: Permit fiscal intermediaries to determine specific covered drugs and conditions, based on general coverage categories and guidelines from HCFA.

Drug-level coverage decisions-whether to cover particular types of drugs for particular conditions or organisms-can theoretically be made at almost any level. The potential decisionmakers range from Congress, which could specify particular drugs in statute, to physicians, who could be permitted to prescribe (and receive payment for) any drug for any condition they deemed appropriate.

Greater levels of regulatory intervention in the decisionmaking process are associated with both greater checks on imprudent physician prescribing and less flexibility to accommodate new, effective drugs and treatment protocols. The choice of who should designate the drugs and conditions covered, therefore, becomes one whose point of compromise depends on the degree to which one values flexibility at the expense of oversight and consistency.

It is unlikely that Congress would choose to take upon itself the burden of identifying specific drugs and conditions to be reimbursed under Medicare. It is also unlikely that Congress would want Medicare to pay for all physician prescriptions. Option 2 thus outlines two intermediate alternatives. Option 2A exercises the greatest regulatory control, permitting coverage only for drugs determined by HCFA to be safe and effective in the home. In option 2B, the basic decision regarding what drugs are generally effective when delivered at home is left to the FIs-those contractors (usually private insurance companies) who would administer the benefit at the local or regional level on Medicare's behalf.

Federal-level decisionmaking would result in the greatest coverage consistency. HCFA has little experience in drug evaluation and is not currently involved in any drug approval process. If HCFA is

12 Alternatively, a patient with fragile veins might have a central catheter surgically implanted to avoid the need for repeated venous punctures.

required to approve drugs for home infusion use, either the agency must retain additional advisory personnel who have clinical experience, or another agency with such expertise (e.g., the Agency for Health Care Policy and Research, or the Food and Drug Administration) must be directed to assist HCFA in this task.

Local decisionmaking offers more adaptability but less consistency across locales (and, thus, presumably somewhat less equity across patients). Many FIs already have some familiarity with home infusion therapy in the context of either their Medicare or their private business, and they have medical advisory structures in place. If option 2B is chosen, administering an HDIT benefit through a few regionalized FIs might enhance coverage consistency (see option 6).

In addition to (or instead of) covering a basic defined set of drugs (whether set by HCFA or FIs), Congress could choose to provide provisional or augmented coverage for drugs that were part of specified demonstration projects. This possibility is discussed in option 11 below.

Patient Eligibility

Option 3A: Cover only patients who can self-administer their therapies (after initial instruction) or who have family caregivers trained to perform this service.

Option 3B: Extend coverage to all patients who can be safely treated at home, including patients who need assistance with their infusion-related or other home health care.

Option 3C: Extend coverage to patients who cannot self-administer, but limit the amount of assistive services such patients may receive.

Many beneficiaries who would prefer HDIT over hospital infusion might require assistance with their infusion or other health care needs in order to go home. However, providing assistive health services greatly increases the costs of care for a patient on HDIT, and the extent to which Medicare covers these services for HDIT beneficiaries would greatly affect Medicare expenditures.

Under option 3A, Medicare would cover HDIT only for patients who can demonstrate the capacity to administer the infusion without the assistance of a paid caregiver.[13] This alternative would restrict the benefit to a small number of patients and offers the surest opportunity to achieve program cost savings. However, it restricts the ability of disabled homebound patients, or those who (with assistance) might be able to avoid hospitalization altogether, to receive HDIT from a professional caregiver.

Under option 3B, any patient meeting basic medical appropriateness criteria could make use of the benefit. However, it would permit unlimited use of assistive home services, no matter how expensive, unless adjunct policies were also in place to limit these services.

Option 3C permits any patient to be eligible for HDIT but restricts the covered benefits that patient can receive. For example, the HDIT benefit might include coverage of daily nursing to accommodate patients with needs for occasional nurse-administered infusions (e.g., up to 10 visits or 20 hours of home skilled nursing per week). To avoid unwittingly paying for assistive services through the home health benefit in this example, HDIT patients could be disqualified from concurrent eligibility for that benefit. This alternative eliminates the possibility of paying for home care for patients who need very extensive services, but it could prevent some patients who currently qualify for home care services from receiving their infusion at home as well.

Alternatively, the HDIT benefit could be very limited in its coverage of assistive services but beneficiaries could be permitted (if they qualified) to retain home health benefit eligibility at the same time. Under this scenario, home health coverage for these dual-coverage patients could be limited to restrain utilization of assistive services. For example, HDIT patients who were homebound could be permitted concurrent coverage for home health services up to a stated maximum limit.[14] This alternative would allow for some assistance while providing an incentive for home providers to accept patients only if their anticipated assistive needs were few. However, it might also result in some underservice or rehospitalization of patients whose assis-

13 For example, a physician might be required to certify that the patient or family member could perform the infusion as a prerequisite for eligibility for the benefit.

14 For example, coverage for concurrent home health benefits could be limited to a dollar amount equal to some percentage of the *average* per-patient home health payment in that area.

tive needs were eventually greater than originally anticipated.

Option 3C might be somewhat complex to administer, since it presumes that the FIs involved can monitor HDIT and home health benefits simultaneously. Its implementation would be most straightforward if both benefits were administered by the same intermediary so that concurrent benefit eligibility could be detected easily (see option 5).

Administrative Options

The choice of how an HDIT benefit is to be administered can be made by Congress, or it can be left to HCFA to decide. Traditionally, the responsibility for administrative decisions has been primarily the purview of the executive branch of the government. Some administrative aspects of an HDIT benefit, however, have broad implications for the shape of the benefit itself. In these cases, Congress may want to provide HCFA with either statutory or nonbinding language to indicate how HCFA should address these issues.

Options 4 through 7 address some of the major decisions that must be made regarding administration of a home drug infusion benefit. These include:

1. how the primary provider responsible for the home benefit is specified;
2. whether an HDIT benefit should be placed administratively under part A or part B of the Medicare program;
3. whether the administration of the benefit should be consolidated under a few regional Medicare FIs; and
4. who should conduct appropriate case approval and review activities.

Provider Designation and Service Integration

Option 4A: For patients needing only HDIT, permit providers of different components of this therapy (e.g., pharmacy and nursing services) to bill separately for their respective components.

Option 4B: For patients needing only HDIT, require that a single certified home infusion therapy provider bill for all services received by that patient.

Option 4C: For patients needing both infusion and other home health services, permit a certified home infusion provider and the HHA provider to bill separately for their respective services.

Option 4D: Require that the primary provider for patients needing both infusion therapy and other home services-i.e., the provider who coordinates services and submits a bill to Medicare--be a certified HHA.

Some Medicare patients will need only HDIT and no additional assistive services in order to continue their medical treatment at home. (In fact, under option 3A above, only these patients would be eligible for the benefit.) For these patients, Congress could permit providers to bill Medicare as they sometimes do other payers, with one or many providers submitting bills according to the specific components of therapy they provide.

However, Congress may wish to ensure service integration and provider accountability by requiring that a single provider bill Medicare for all HDIT services provided to that patient. As was the case under the Medicare Catastrophic Coverage Act, the primary HDIT provider could be required to meet detailed criteria, as outlined in regulations, to be certified as a qualified HDIT provider.

Many Medicare patients medically stable enough to go home on HDIT, however, may need basic home health assistive services in order to function in this setting. Many (if not most) of the major HDIT providers are not Medicare-certified HHAs and do not provide basic home nursing, therapy, and home health aide services. For these patients, Medicare could permit separate billing by the respective HDIT and HHA providers (option 4C), with one or the other required to coordinate the two types of services; or, Medicare could require a certified HHA to bill for and coordinate all in-home health services provided to a given patient, including HDIT (which might be provided under contract to the HHA) (option 4D).

The coordination of infusion and other home health services is an important issue for beneficiaries, providers, and the Medicare program alike. For beneficiaries, dealing with two separate providers of home care services might mean duplications and gaps in services, with no single source of contact for coordinating or discussing the overall care with the patient. If a single HHA provider is responsible for both sets of services, coordination of these

services would be done by that HHA. If separate HDIT and HHA providers were recognized (as in option 4C), Medicare might want to require one of the providers (or an outside case manager) to undertake the coordination responsibilities.

For providers, permitting separate HDIT and HHA billing has the advantage of leaving the billing for a service to that provider with the most background in that service. There would be little need for HHAs to learn new HDIT-related billing and oversight responsibilities unless they undertook them voluntarily. Separate billing is preferred by many HDIT providers, because most are not currently certified by Medicare as HHAs (and some reportedly cannot do so because of certificate-of-need laws in their States that restrict new HHAs).

The Medicare program, on the other hand, might find single HHA-based billing simpler once HHAs learned the necessary procedures. Single billing would also reduce the difficulty of identifying and avoiding duplicate payment for HDIT and other home nursing services. Since home health is a Part A service unless the beneficiary has no Part A coverage, Medicare Part A intermediaries (rather than Part B carriers) would be the logical administrators to deal with claims if only HHA single-billing were permitted. However, this option might require considerable training of HHAs to familiarize them with HDIT and the necessary billing procedures.

Note that even if single HHA billing were required for patients receiving both HDIT and other home health services, Medicare could still permit HDIT-only providers to bill for infusion-only patients. In this case, claims might be handled by either Part A or Part B FIs, depending on the intent of Congress and the Medicare program (see option 5).

Administrative Placement

Option 5A: Make HDIT a Part A benefit.

Option 5B: Make HDIT a Part B benefit.

Option 5C: Make HDIT a benefit under both Parts A and B, depending on the patient's circumstance and concordant benefits.

The choice of administrative placement for an HDIT benefit affects who administers it and how easily it can be integrated with other Medicare benefits. Medicare Part A generally covers hospital, SNF?, home health, and hospice care and is administered through one set of FIs. Medicare Part B covers physician and laboratory services, hospital outpatient and ambulatory surgical services, and DME and is administered through a separate set of FIs. The Parts A and B FIs are private insurance companies, but only rarely does the same company fill both roles in its given locality.

At present, both Part A and Part B benefits overlap somewhat with a potential home drug infusion benefit. Existing home health benefits are usually under Part A and administered by 10 regional FIs, but home health services are also a Part B benefit for beneficiaries not eligible for Part A coverage. (In the latter case the benefit is still administered by the Part A FIs.) TPN, an existing infusion benefit, is a prosthetic device benefit under Part B and consolidated under two regional Part B FIs. DME benefits are usually administered through Part B FIs, but DME supplied by an HHA as part of the home health benefit is administered through the 10 Part A home health FIs. Hospice care, which sometimes includes home infusion therapy, is a Part A benefit; outpatient infusion and physician and laboratory services are Part B benefits.

Thus, the choice of where to place an HDIT benefit administratively depends in part on how it is to be integrated with existing benefits. If the benefit is to be linked with home health benefits, it would be administratively simplest to place it under Part A. If, however, it is to be entirely distinct from home health nursing, it would be simpler to place it under Part B, where some administrative experience with reimbursing for the component equipment and drugs is developing. Finally, it could be administered under Part A for some patients (e.g., those also qualifying for home health benefits) and under Part B for others (e.g., those needing no adjunct services) (see option 4).

The split of bills for patients receiving infusion services between Part A and Part B Fls could be problematic, since it would require all administrative contractors to gain some expertise in handling infusion claims and would increase variation in that handling. On the other hand, if home health and infusion providers were permitted to bill separately, Medicare might find it difficult to identify duplicate claims for home health nursing services.

One way to minimize claim-handling variation in the former case might be by consolidating FIs for the purposes of administrating this provision (option 6).

Fiscal Intermediary Consolidation

Option 6: Require that the benefit be administered through a few regional FIs.

Regardless of whether an HDIT benefit is placed under Part A, Part B, or both, Congress (or HCFA) may want to consider consolidating the administration of the benefit under a few regional Medicare administrative contractors. Such a consolidation has precedent both under Part A (for home health benefits) and under Part B (for TPN benefits).

The great advantage of consolidation is that the few administrative FIs can amass greater experience in administering the benefit, leading to more consistent coverage decisions, more rapid claims processing, and more information with which to update coverage decisions or payment amounts. In addition, the fewer number of administrative organizations means that the potential for widely varying and inconsistent coverage policies would be reduced. The advantage of greater claims experience might be especially important if the benefit were split between Part A and Part B, depending on the particular patient and circumstances (see option 5C).

The primary disadvantage of regional FIs is that the crossing of traditional contractor boundaries might pose difficulties for peer review organization (PRO) review, since PROS are located in each local contractor area. To overcome this disadvantage, the benefit might need to be overseen by a few regional PROS, corresponding to the regional intermediaries or carriers. To date, however, HCFA has relatively little experience in designating PROS with responsibilities across local contractor lines whose activities include prior authorizations.

Case Review

Option 7A: Do not require preauthorization for HDIT.

Option 7B: Require PROS to preauthorize some or all HDIT patients.

Option 7C: Require FIs to preauthorize HDIT patients.

Option 7D: Require PROS to retrospectively review some home infusion patient claims.

A critical element in the safe and effective delivery of HDIT is patient screening to ensure that hospital discharge (or, for nonhospitalized patients, drug therapy) is appropriate. Performing patient screening is one of the functions of HDIT providers. If they do it well, Medicare oversight—i.e., preauthorization-of HDIT patients at the onset of home therapy may not be necessary.

It may be difficult for Medicare to assure itself that HDIT patients are being appropriately screened, however, especially in the frost years when there is little experience with an HDIT benefit. In particular, Medicare may be justifiably concerned about premature hospital discharge. One detriment to a Medicare HDIT benefit is the strong financial incentive it could provide to both hospitals and home care providers to remove patients from the hospital, even when home care may be inappropriate or the patient is unwilling to be discharged. In the case of patients who are not hospitalized at the time HDIT is prescribed, Medicare may still wish to be assured that the patient can be safely treated at home. And in all cases, Medicare may wish to document who will be responsible for therapy and assure that the prescribed infusion therapy meets some basic criteria of medical necessity (e.g., oral drugs are not effective for the given condition).

There are two logical parties to perform HDIT preauthorization. First, the FIs who would later process the claim could conduct the review. Alternatively, PROS could give the preauthorization.

PROS are physician-run private organizations that contract with Medicare to review the appropriateness and necessity of medical interventions in a variety of settings, including hospitals. They are capable of detailed medical assessment and would probably be the most appropriate reviewers if the prior review were to involve an extensive discussion of the patient's therapy and condition. (The MCCA required PROS to conduct preauthorization review of all patients recommended for HDIT. In addition, HCFA's proposed regulations required PROS to approve prescription changes and other alterations made during the course of therapy, and to conduct retrospective review of a random sample of HDIT cases.) The disadvantage of this proposal is that PROS are poorly organized for quick response (as would be required where home discharge is imminent), and the extensive review that they are most qualified to provide is time-consuming, expensive, and would probably delay patient discharge somewhat.

FIs, in contrast, have traditionally had relatively less in-house medical expertise[15] but are more geared to day-to-day decisionmaking and detail. FIs thus might be more appropriate organizations to conduct preauthorization if the goal is a less comprehensive and less expensive check on basic appropriateness. For example, a FI-based prior approval mechanism might be simply to tentatively approve home therapy based on affirmative answers to a short list of screening questions, with final approval for payment made retrospectively by claims personnel on the basis of documentation in the record for these questions. Since brevity would be one of the goals of preauthorization in this case, quick turnaround (e.g., within 24 hours) could also be a requirement.

If FIs were judged to be the appropriate organizations to conduct prior review, it may still be desirable for PROS to participate in the development of the screening questions. Infusion professionals (e.g., infectious disease physicians, IV specialty nurses) could also be involved.

Prior authorization of all patients beginning HDIT may not be necessary, particularly in the long run if concerns about premature hospital discharge prove unwarranted. For drugs that are relatively safe (e.g., many antibiotics) and for which the indications are clear, issuing clear instructions to providers and conducting retrospective review may be sufficient.

Accordingly, in addition to requiring preauthorization of some home care cases, Congress or HCFA could require PROS to perform a detailed retrospective review of the appropriateness of care of a sample of claims to identify problems of care.[16] The review could be a simple random sample of cases (e.g., 10 percent of all claims). The review could be augmented by targeted review of all claims in certain categories indicative of possible problems (e.g., all claims associated with a beneficiary complaint; all claims in which the patient died or was rehospitalized within 30 days after home therapy; all claims for certain categories of drugs).

Payment Options

The way in which Medicare pays for HDIT would affect the shape of the industry, the willingness of providers to offer services to Medicare patients, the quality of the services provided, and the costs to Medicare. Options 8 and 9 deal with how Medicare might pay HDIT providers, whether providers will be required to accept Medicare assignment to serve Medicare patients, and the different ways Medicare might choose to compensate physicians for their services relating to a course of home infusion therapy.

Provider Payment Methods

Option 8A: Pay for the various components of an HDIT benefit under existing payment mechanisms that apply to home health, DME, and other benefits.

Option 8B: Pay for HDIT on the basis of actual costs, with a cap on the total costs allowed.

Option 8C: Pay a prospective per-diem rate for HDIT services.

The potential ways of paying for an HDIT benefit include both retrospective methods, in which the amount of payment is determined after the service is delivered; and prospective payment, in which the fee is determined before the service takes place. Retrospective methods include cost-based payment (the current method of paying for home health and hospital outpatient services) and charge-based payment (which historically has been the method of paying for DME and physicians' services). Prospective methods are varied and generally rely on some form of a fee schedule. Fees maybe established for each individual item or service, or these services may be "bundled' across time into, for example, a per-diem or per-discharge payment. Fees may either be set by the payer or be established on the basis of negotiation or provider competition.

Although any of these methods could theoretically be applied to HDIT, only three are sufficiently

15 Several carriers told OTA that their in-house medical expertise has increased over time and is now comparable to that in PROs. OTA has nOt independently evaluated this claim.

16 Under the MCCA, health maintenance organizations (HMOs) would have been excluded from PRO review for this service. However, HMOs that provide HDIT may face the same incentives as non-HMO hospitals to discharge patients to home care with inadequate support. Thus, PRO review of Medicare home infusion patients in HMOs and other capitated plans patients maybe justified.

well developed that they could, if desired, be implemented immediately. Of these, a method combining cost- and charge-based reimbursement would be the simplest to implement. In essence, this method would simply extend current rules (e.g., cost-based payment for home health services and charge-based payment for drugs, equipment, and supplies) where they applied and augment the existing system with refinements where necessary (e.g., better drug codes, allowances for pharmacy services). Non-HHA infusion providers might need to be permitted to bill for nursing (in a manner analogous to home health nursing visits) when the nursing visits were for infusion. This method is easily compatible with a policy that allows different providers to pay for different components of HDIT. It would probably have few negative consequences for quality or access to care, but it also offers the fewest possibilities for cost control.

All-cost-based reimbursement also offers incentives to provide high-quality, accessible care to Medicare beneficiaries, but it may be somewhat inflationary. Placing a capon allowable costs might reduce cost increases to some extent. All-cost-based reimbursement would be relatively easy to implement if HHAs were the primary providers, but HDIT-specialty providers have little experience with cost reporting. For these providers, this payment method would require some administrative effort. In any case, this payment method would probably require that a primary HDIT provider bill for all HDIT-related services in order for provider-specific Medicare costs to be assessed accurately.

Prospectively set rates (e.g., per-diem rates) for HDIT have been used successfully by private insurers, and more information is available to set rates now than at the time the MCCA was passed. This method offers the greatest possibility for cost control, but it could endanger patient access and quality of care if rates are low and quality of care cannot be monitored adequately.

If prospectively set rates are chosen as the method of payment for HDIT, bundling at least nursing services, supplies, and equipment into a single rate (or set of rates) may reduce paperwork burdens and system ''gaming.'' Continual advances in new technology and potential tradeoffs between nursing needs and equipment costs for some technologies means that, if payment were according to an itemized fee schedule, Medicare might find it difficult to keep up with changes in the therapy and still keep costs under control.

Competitively set prospective rates offer some advantages over HCFA-designated rates. Since rates are set according to the market based on provider bids, the data problems HCFA might otherwise encounter (e.g., setting rates too high or too low due to lack of information on provider costs) would be relatively less important. However, the need to compete and contract separately in each area of the country, and the need to monitor quality of care very closely, might make competitively set rates administratively very burdensome and costly. In addition, if contracts were awarded to only a few providers, the market advantage given to these providers might result in future market concentration. Thus, in later contracting rounds, there might be fewer providers bidding for contracts, and higher future payment rates.

Other payment methods-for example, bundling the payment for HDIT into the hospital's DRG payment—are also possible, but it would be difficult to implement these methods quickly. Some of these methods could be tested through demonstration projects if desired (see below).

Regardless of the payment method chosen, Medicare might want to take measures to limit beneficiary liability for charges greater than what Medicare pays. Private insurers have successfully implemented 'preferred provider' programs, under which providers agree to meet quality standards and accept the insurer's payment rate as payment in full, in exchange for the likelihood that more of that insurer's patients will use the provider's services. A similar program requiring mandatory assignment for HDIT providers serving Medicare patients would reduce patients' risk of being billed for charges in excess of the Medicare payment rate. A lack of providers willing to participate could be one indicator that Medicare payment rates were set too low.

Physician Reimbursement

Option 9A: Pay physicians for their additional supervisory time in HDIT cases on the basis of existing fee-for-service methods.

Option 9B: Pay supervisory physicians a fixed rate (e.g., per patient or per day) for patients on HDIT.

Option 9C: Do not pay physicians for supervisory and advisory activities related to oversight of HDIT.

OTA found that active physician participation in a patient's home infusion care enhances the quality of that care and may help prevent potential untoward effects. In the hospital, physician involvement takes the form of frequent (usually daily) visits, each of which is often separately billable to Medicare. For patients in home care, however, physicians face substantially fewer opportunities to bill for services. Patients have fewer billable physician visits, while physicians spend time monitoring and adjusting therapy outside of visits and consulting with pharmacists, nurses, and patients over the telephone. None of these latter activities are currently reimbursable under Medicare.

Some physicians and home infusion providers have devised compensation mechanisms to counteract the financial disincentives related to payer policies. Some infusion providers, for example, reputedly pay physicians "consulting fees" in exchange for referrals. In other cases, physicians are co-owners of an infusion provider and thus share in profits that arise from referring patients to that provider. These arrangements may arise out of a legitimate desire to influence the quality of care provided and to receive some kind of reasonable compensation for the physician services associated with home care. Nonetheless, physicians have a virtual monopoly on referrals to HDIT providers. Physician compensation that is linked to the patient utilization of a particular provider introduces the possibility that physicians will refer patients to a higher-cost or lower-quality service in order for that physician to receive financial benefits. Even in a more benign form, physicians may be less active in seeking out the best provider for their patients when they share in the profits from a referral.

Medicare can, if it wishes, prohibit physicians who are co-owners of an HDIT provider from receiving payment, and existing Medicare anti-kickback provisions prohibit payment where physicians gain a fee for referral. If these forms of compensation are banned, however, many physicians will continue to be financially penalized for referring patients to home care. To avoid such a penalty, Medicare could pay physicians more comprehensively for the services they provide to HDIT patients.

Although there are many possible permutations on physician payment, one possibility is to permit physicians to bill for the time they spend in certain activities relating to overseeing the care of HDIT patients. Under this option, for example, physicians might be permitted to bill for the time spent in telephone consultation during a patient's course of home therapy. The advantage of this option is its simplicity and compatibility with current billing methods. Its primary disadvantage is its "blank check' characteristic; there are few ways to confirm that the time billed was actually spent on issues relating to a particular patient's HDIT. This option also sets a precedent for billing for telephone services and home care oversight generally, which could substantially increase Medicine costs.

A second option is to pay physicians a flat fee for the management of patients on HDIT. This fee could be a nominal one intended to cover only the average costs of oversight time exceeding what would be normally expected of a home care patient. Alternatively, the fee could be intended to cover all physician services relating to the infusion therapy during the course of therapy, including office and home visits. The amount could be set per day or per episode of therapy; it could vary depending on the type of therapy, the expected or actual duration of therapy, or other factors. There is a precedent for such a payment method; under the Medicare End-Stage Renal Disease program, physicians overseeing the dialysis treatment receive a flat monthly fee per patient. Additional billing is permitted for services performed for unrelated conditions (e.g., treating a broken arm).

A potential drawback of a flat comprehensive fee (rather than a daily fee) is the financial incentive to underprovide services. Under a comprehensive fee, fewer visits do not bring commensurately less revenue. Medicare could choose to assume that this problem would be minimal due to physicians' desires to provide good care to their patients, and their desire to avoid legal liability for poor care. Or, Medicare could set a mandatory minimum number of visits to ensure at least a basic level of service. Fees could vary depending on the type of therapy involved and whether the patient was on multiple therapies under the direction supervision of several physician specialists.

Research and Demonstration Options

A great many things that Medicare might want to know about HDIT are unknown or the subject of controversy. Areas of uncertainty range from clinical questions about the use of specific therapies in the home to questions about the needs of elderly HDIT patients and questions of costs and payment for HDIT. Many of these uncertainties could be addressed through specific research or demonstration projects aimed at investigating the particular issue.

Options 11 through 19 present examples of possible studies. Although this list is by no means exhaustive, it includes some of the major areas of controversy or uncertainty in which the findings could have a significant effect on the policies Medicare might choose to pursue. These projects could be undertaken to refine an existing basic HDIT benefit that had already been put in place. Alternatively, demonstration projects could predate a benefit, with the findings used to determine the shape of a later national HDIT Medicare policy.

Clinical Studies

Option 11: Provide provisional or augmented coverage for drugs administered by HDIT providers participating in certain clinical studies.

Medicare does not usually cover experimental drugs or procedures. Given the uncertainty about home use even for some drugs commonly used in hospitals, however, Medicare could choose to develop a framework to investigate drugs for their appropriateness in HDIT and their eligibility for Medicare coverage in that setting.

For example, Congress could authorize provisional coverage for drug infusion therapies for which insufficient evidence on home use in the Medicare population exists, but for which there are *a priori* reasons to think that the drug is likely to be effective in this setting and this population. Provisional coverage could be limited to drugs that had already received Food and Drug Administration (FDA) approval for use in the hospital, and participation in an organized research protocol (with enhanced data collection) that had been approved by HCFA could be required of providers for reimbursement during the provisional period. Such studies could gather economic as well as clinical information.

Congress could also choose to authorize provisional coverage for some projects involving drugs with greater clinical uncertainties. Such projects might be used to address the relative effectiveness of an approved drug for a new use that was likely to be long-term and applicable to the home setting. For example, a project might provisionally cover dobutamine while collecting and examining the evidence that this drug actually does improve health when used as an intermittent long-term therapy. This type of project involves greater potential for provisionally funding drugs that will eventually be proven ineffective, however. Congress might wish to distinguish between studies of drugs that have previously been proven effective for a particular use in the hospital, and those for which effectiveness for the use itself is still in doubt.

Cost Studies

Option 12: Examine the resource costs of providing HDIT and the economic characteristics of the HDIT industry.

An important problem in determining an appropriate method and level of Medicare payment for HDIT is that the true costs of providing HDIT are unknown. Existing studies of the "costs" of HDIT often rely on provider charges to estimate costs. However, charges (i.e., provider-assigned prices) and costs (the true resource costs faced by the provider) are by no means the same and may vary across therapies, patients, and providers. Differences in provider-specific costs would be especially useful for Medicare to understand, so that payment rates can accommodate those differences where desired without unnecessarily increasing Medicare expenditures.

Option 13: Examine the relative costs of providing drug infusion therapy in home and outpatient settings.

Although the focus of this report is home therapy, drug infusion therapy is also sometimes provided in outpatient clinics. Proponents of outpatient therapy argue that it enables better quality control, greater physician involvement, and greater economic efficiencies because there is no need to send a nurse to every patient's home. If these arguments are valid for at least some patients and providers, Medicare may want to be especially careful not to put in place an HDIT benefit that would unintentionally discourage patients from outpatient infusion therapy where

it is available. Understanding the relative costs and uses of outpatient and home therapy would help inform such a policy.

Option 14: Examine the use of basic home health services, and the need for infusion assistance, among elderly patients on HDIT.

As mentioned above, an HDIT benefit could be limited to patients who (with family caregiver assistance) were capable of self-care. Many other beneficiaries, however, might also prefer HDIT to institutional treatment. A major question for Medicare is the extent of this potential demand, the characteristics of the patients who would use adjunct services, and the costs of the home health services involved.

A demonstration project could examine this question either generally or for one or more groups of beneficiaries of particular interest to Medicare. Groups of potential interest, for example, might be homebound beneficiaries currently receiving home health services who develop a need for infusion therapy; patients needing help with the actual infusion but no other home health assistance; and patients for whom it is anticipated that inpatient hospitalization for drug therapy could be avoided if HDIT and other home health services were available.

Payment Studies

Option 15: Examine different potential methods of paying for HDIT.

Although cost- and charge-based payment methods could be applied to HDIT with relatively modest administrative effort, other methods are more difficult or rely on less certain information. Per-diem methods, for example, are feasible at present, but the information on which appropriate rates could be based is scanty. A demonstration project testing a preliminary rate for its effects on provider participation and quality of care would add greatly to that information base. Other payment methods that could be tested include:

- competitive bidding methods;
- per-diem methods in which components were "bundled' in various ways (e.g., the per-diem rate might include or exclude such items as DME, nursing services, pharmacy services, and laboratory services);
- per-patient prospective payment methods based on episodes of care; and
- hospital-based payment, in which the hospital might receive the HDIT payment as a DRG add-on and be responsible for providing or arranging for all care, whether inpatient or outpatient.

Option 16: Examine the feasibility and effects of paying hospitals less than the full inpatient rate for patients subsequently discharged to HDIT.

A major barrier to Medicare program savings in the first years of an HDIT benefit is the fact that hospitals are entitled to receive the full DRG-based payment for all patients in that DRG, even if a patient is discharged to HDIT after a few days. One possible solution to reduce expenditures would be to pay hospitals less than the full DRG amount for patients discharged to HDIT. For example, if the discharge destination on a patient's hospital bill is recorded as HDIT, the inpatient stay might be treated as a transfer, with the "transferring" hospital receiving a prorated amount depending on the actual inpatient length of stay.

A philosophically troublesome aspect of such a "transfer" policy is that it contradicts the basic theoretical structure of Medicare's hospital payment system, which is intended to reward hospitals that behave efficiently (e.g., by discharging patients quickly). In addition, the actual effects of such a policy on hospital discharge behavior and Medicare expenditures are unclear. For example, hospitals might simply encourage physicians to discharge such patients only at the point where the hospital had recouped the full DRG payment. On the other hand, such a policy might have some effect on expenditure reduction even in the event of such hospital behavior.

Option 17: Examine alternative methods of paying for drug infusion therapy in SNFs and hospital swing beds.

Where patients are medically stable but need continual supervision or substantial assistive care in addition to their drug infusion therapy, institutional care that is less intensive than hospital inpatient care may be the most appropriate and least expensive. At present, however, there appear to be considerable staffing-related problems and some financial disincentives to providing drug infusion therapy in SNF

and swing-bed settings. Other methods of paying for such therapy in these settings warrant investigation.

Option 18: Examine the effects of an HDIT benefit on rural and inner-city hospitals.

If an HDIT benefit is put in place, most hospitals will be able to discharge relevant patients to a home care provider in their area. These hospitals will benefit financially by doing so, because they receive the full DRG payment for each patient regardless of the actual length of the inpatient stay.

Some hospitals, however, may not be able to discharge patients easily. Some rural hospitals, for example, may be located in areas with no qualified HDIT provider. Inner-city hospitals may serve patients who live in high-crime areas that local providers may be unwilling to serve. Thus, it is possible that hospitals in these categories may be financially disadvantaged, through no fault of their own, by their inability to discharge patients to HDIT and lower their costs. A study of hospitals that are potentially at risk of being disadvantaged could determine whether Medicare policies needed to accommodate this factor.

Quality Studies

Option 19: Examine the outcomes of HDIT under various conditions (e.g., different types of patients and therapies) to determine which measures might be appropriately used as indicators of good- or poor-quality care.

Medicare's ability to monitor the quality of care provided under an HDIT benefit is crucial. Participating providers, for example, might be required to show that their record on care quality was acceptable before being able to renew their Medicare certification. Indicators of poor quality could be used to screen cases for more in-depth retrospective review. And certain payment systems, particularly prospective payment systems with fixed rates, include incentives to underprovide care, making Medicare's ability to detect and censure poor-quality care even more critical.

Despite their importance, measures of the quality of HDIT are not well-studied and reported in the literature. Examples of measures that deserve study include:

- average complication rates (e.g., the rate of catheter-related infection) among different types of patients and therapies;
- differences in complication rates, rehospitalization rates, and other factors that are related to different drug delivery systems (e.g., whether patients on simple gravity drips experience more complications of therapy than patients using more sophisticated infusion devices);
- the different factors that affect patient satisfaction with therapy; and
- whether provider-specific factors (e.g., contracting v. providing in-house services) are consistently related to other possible quality measures.

Because HDIT technologies have been changing so rapidly, even professional associations that establish care standards (e.g., the frequency with which catheters should be changed to avoid infection) are hard-pressed to keep their recommendations in pace with technological change.

The Federal Government could fund studies to examine various outcome measures to determine which measures can most appropriately be used to monitor the quality of HDIT care provided to Medicare beneficiaries. Such studies could be done in conjunction with a new HDIT benefit or as part of a larger demonstration study of HDIT.